DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

September 2, 1998

Dear Medical Device Manufacturer:

On January 21, 1998, Department of Health and Human Services Deputy Secretary Kevin Thurm wrote to you and, in follow up, on June 29, 1998, I wrote asking you to provide information regarding the Year-2000 compliance status of your products to FDA's Year-2000 web site. This web site is intended to assist purchasers and users of biomedical equipment in assessing the impact of the year 2000 on their equipment. To provide users with sufficient time to assess their vulnerability, as well as to plan and institute corrective measures, we had hoped this web site would by now be a comprehensive Year-2000 information resource.

However, our records indicate that we have not heard from a number of companies to which we sent letters, including your firm. There may be several reasons we have no record of your reply. Perhaps the letters were misdirected or lost, or your response was sent but has not yet been received, or you responded under a different business name. We expect that some companies are still assessing the status of all of their products and have delayed responding until that effort is completed. Nonetheless, because it is very important that manufacturers provide information promptly, **I am writing again to ask that, within the next two weeks, you respond with the needed information, or at least indicate you are working on a full response.**

Please respond under the name to which we addressed this letter. You may do so either electronically, using the data submission form available on the FDA web site, or by mail. In your response, please indicate, as appropriate:

- that medical devices you market and have sold are not Year-2000 vulnerable,
- that medical devices you market and have sold are all Year-2000 compliant,
- that you are providing specific information regarding those products that are not compliant or whose assessment is currently incomplete (instructions for submitting this information and the data requested are described in the enclosure),
- that you are working on an assessment and will post the results by [date], or
- that you have responded under a different business name and the name to which this letter was sent should be deleted from our list.

The Federal government's health services agencies are keenly aware of the need to provide information to healthcare facilities. Industry groups have also taken a stand. The Health Industry Manufacturers Association (HIMA), the industry's largest trade association, has taken the position that the industry "must make every effort to ensure that information about the year 2000 compliance status of medical devices is made available" to health care providers. The Medical Device Manufacturers Association has

also urged its membership to provide this information. And the U.S. Congress is concerned – it has held three oversight hearings on this subject, and some members of Congress are contemplating legislation that would make posting information compulsory. We have been asked to provide Congress with the names of manufacturers who have not responded to our previous requests for information.

I encourage you to provide whatever information is currently available, indicating those specific products whose assessment is incomplete. It is important that you respond even if you have no vulnerable products or if you are in the process of preparing your response. Update information for those products may be provided as the assessments are completed. We intend to post to the FDA's Year-2000 web site the names of all manufacturers sent this letter. For each manufacturer, we will show the information on product status that we have received by September 22. If we have received no information by September 22, 1998, we will state that the manufacturer has not supplied it. We plan to update this information periodically thereafter.

The Year-2000 database, information about this issue, and forms for electronic submission can be found on the "Year 2000" section of the CDRH web site at the URL http://www.fda.gov/cdrh. Thank you for your prompt attention to this request.

Sincerely,

D. Bruce Burlington, M.D.
Director
Center for Devices and Radiological Health

Enclosure: Instructions

Medical Device and Scientific Laboratory Equipment
Year 2000 Compliance Information

The Federal Government has established a World Wide Web site to provide information related to the Year 2000 compliance of medical devices and scientific laboratory equipment. The general public, including government agencies that purchase and use biomedical equipment, and health care and research communities will have access to this web site. Manufacturers of biomedical equipment are urged to provide the information described below regarding the Year 2000 compliance status of their products, including both current and previously manufactured products.

For the purpose of this product status reporting, Year 2000 compliance for medical devices and scientific laboratory equipment means that the product accurately processes and stores date/time data. This includes, but is not limited to, calculating, comparing, displaying, recording, and sequencing operations involving date/time data during, from, into, and between the twentieth and twenty-first centuries, and the years 1999 and 2000, including correct processing of leap year data.

This definition is a slight modification of the "Year 2000 Compliance" definition used in the Federal Acquisition Regulations for information technology products to address medical devices and scientific laboratory equipment (see 48 CFR Part 39.002). The intent is that for products to be Year 2000 compliant they must function as intended or expected, regardless of the date. A manufacturer's reporting of Year 2000 compliance status should include all products (units) produced which could still be in service.

Manufacturers are requested to provide one of the following two items of information:

- **A certification that all of the manufacturer's products are Year 2000 compliant or a certification that the date problem is not applicable to any of their products. (This certification can be made only if the manufacturer has assessed the compliance status of all products. Otherwise, a status of AI (see below) with date must be reported for those products not yet assessed.)**

- **A listing of products which have Year 2000 compliance problems (are not compliant under the definition given above) with sufficient information to identify the specific product (as described below).**

    - Type of product (Generic description of product. For medical devices, the generic type of device as used in the device classification regulations of 21 CFR Parts 860 - 892 may be an appropriate description.)
    - Owner/Operator Number if manufacturer is an FDA regulated firm
    - Original manufacturer (if different from company providing information)
    - Model number
    - Specific serial numbers (if appropriate)
    - Software version number
    - Brief description of the date-related problem
    - Solutions to be offered by manufacturer to mitigate problem - one of the following codes should be used to indicate the solution to be provided for the product:

SU/date -	Upgrade to software will be available by (date) at no cost to purchaser.
SU-C/date -	Upgrade to software will be made available by (date) at a cost to purchaser.
HU/date -	Upgrade to product (hardware and software) will be made available by (date) at no cost.
HU-C/date -	Upgrade to product (hardware and software) will be made available by (date) at a cost.
M -	Minor date-related problem with product, presenting no adverse health impact on product function and for which manufacturer will not provide a correction/upgrade.
O -	Product is obsolete or beyond reasonable useful service life and no upgrade will be provided.
AI/date -	Assessment of compliance status is currently incomplete but is underway and information will be made available by (date).

- Point of Contact to discuss product information including name. address. telephone number, fax number, and e-mail address.

The information may be provided using one of the following methods:

- **Posting the certification of total product compliance or non-compliant product information on a manufacturer operated web site and provide the URL for the web site to the FDA at either of the addresses given below.** The FDA will incorporate a link to the manufacturer's web site from the FDA-maintained site providing the product Year 2000 compliance data. A condition imposed by the government on providing this link is that the link be directed to a portion of the manufacturer's web site which directly provides the full data elements or certification described above and not to a page providing other types of information or product promotion.

- **Submitting information directly to FDA electronically by completing the data entry form provided on the government web site at http://www.fda.gov/cdrh/yr2000/y2kform.html using the USER ID = and the PASSWORD =**

- **Mailing the certification of total product compliance or information regarding non-compliant products to the address listed below, for posting on the government web site.**

Mailing address: Food and Drug Administration
Attn: Y2K Medical Devices Coordinator
Center for Devices and Radiological Health
Mail Code HFZ-Y2K
9200 Corporate Boulevard
Rockville, MD 20850

In order to best serve the industry, as well as recognizing the limited time available before the Year 2000, we ask all manufacturers to respond within sixty days. The provision of information, by either of the methods described above for posting on the government web site, signifies that the information provided is true and complete and covers all of the manufacturer's products to the best of the manufacturer's knowledge. Manufacturers who are unsure of the status of a product should report it as code AI until the assessment is completed.

The request for web site posting of product information on noncompliance status or total compliance certification is designed to provide an opportunity for manufacturers to communicate and better serve customers in a responsible and proactive manner, and avoid the necessity for manufacturers and vendors to field numerous calls and letters from individual organizations. The information you provide will prevent Year 2000 problems from endangering the nation's patient care and health research activities.

The public will be informed via the web page that:

> There is no assurance that manufacturers who fail to respond to this request are Year 2000 compliant.
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> The information that resides on this web site has been provided by the manufacturers of biomedical equipment. Users or potential purchasers of equipment should independently verify compliance of specific, critical products.

If you have questions regarding this survey or web site, you may contact Gayle Finch, Director of the Office of Information Technology Planning and Investment, Office of the Secretary on 202-690-5515. Questions on technical aspects of data submission or electronic communications should be addressed to Stuart Carlow, Director of the Division of Information Dissemination, Center for Devices and Radiological Health, FDA at 301-594-4754 or via e-mail to sac@cdrh.fda.gov.

Product Information Form

Complete this form for EACH biomedical equipment product that has a Y2K date related problem or whose assessment is incomplete.

1.	Type of Product	
2.	Model Name or Number	
3.	Original Manufacturer	
4.	FDA Regulated	☐ YES ☐ NO
5.	Serial Number(s)	
6.	Software Version Number(s)	
7.	Description of Date-Related Problem	
8.	Solution to be Provided by Manufacturer:	☐ Software Upgrade at NO COST* ☐ Software Upgrade at COST* ☐ Hardware Upgrade at NO COST* ☐ Hardware Upgrade at COST* ☐ Product Obsolete — No Upgrade ☐ Minor Problem — No Adverse Affect/ No Upgrade ☐ Assessment in Progress*
9.	Date Solution will be provided:	Month Day Year / / **Provide date the upgrade/assessment will be available.*

Please note: *Report only products which have Y2K or other date related problems. Submission of information for one (1) or more products is certification that all other products produced and not reported here, are not impacted by the Y2K or other date-related problems.*

Please Return Form to:

Food and Drug Administration
ATTN: **Y2K Biomedical Equipment Coordinator (HFZ-Y2K)**
Center for Devices and Radiological Health
9200 Corporate Blvd.
Rockville, Maryland USA 20850

Report your Y2K product status electronically at: http://www.fda.gov/cdrh/year2000.html

Thank You for Your Submission!

(Duplicate this form as necessary.)